DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Spectracef
Docket No.: 03E-0036

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

JUL 13 2003

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 4,839,350, filed by Meiji Seika Kaisha, Ltd., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Spectracef, the human drug product claimed by the patent.

The total length of the regulatory review period for Spectracef is 1,461 days. Of this time, 851 days occurred during the testing phase and 610 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: August 31, 1997.

   The applicant claims August 30, 1997, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 31, 1997, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: December 29, 1999.

   FDA has verified the applicant's claim that the new drug application (NDA) for Spectracef (NDA 21-222) was initially submitted on December 29, 1999.

3. The date the application was approved: August 29, 2001.

   FDA has verified the applicant's claim that NDA 21-222 was approved on August 29, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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